REMARKS

This paper is responsive to the Office Action dated September 21, 2006, which is the first action on the merits of the application.

Claims 1-20 were previously pending in the application and under examination. Upon entry of this Amendment, claims 12 and 17 are canceled, and claims 21-32 are added. The added claims fall within the group under examination. Accordingly, claims 1-11, 13-16 and 18-32 are now pending in the application and under examination.

Applicant acknowledges with gratitude that the restriction previously made between claims 1-16 and claims 17-20 has been withdrawn. Applicant also is grateful that the Examiner has considered the information provided in the IDS filed with the application.

Further consideration and allowance of the application is respectfully requested.

Claim amendments:

Entry of the amendments does not introduce new matter into the disclosure. The amended claims are supported by the claims as previously presented. The new claims are supported at various places in the specification and claims as previously presented, such as the following:

Claim 21	Claim 7 as previously presented
Claim 22:	Claim 1 as previously presented
Claim 23:	Claim 11 as previously presented
Claim 24:	Claim 12 as previously presented
Claims 25 & 26:	Claim 1 as previously presented; page 55, lines 32-33
Claim 27:	Claim 4 as previously presented
Claim 28:	Claim 7 as previously presented
Claim 29:	Claim 14 as previously presented
Claim 30:	Claim 1 as previously presented; page 55, lines 32-33
Claims 31 & 32:	Claims 1, 11, and 12 as previously presented

Duplicate claims:

Duplicate wording between claims 6 and 7 has been resolved by amending claim 6. Applicant is grateful to the Examiner for identifying this error.

Rejection under 35 USC § 112 ¶ 2:

Claim 3 stands rejected for being a method that hybridizes. This has been fixed by an amendment to the claim. Withdrawal of the rejection is requested.

Rejections under 35 USC § 112 ¶ 1:

Claims 1, 4-5, 8-17, and 20 stand rejected for covering promoter variants with no particular function. Applicant disagrees, since the previous wording of the claim has an ultimate function that required that the promoter have promoter function. Nevertheless, the base claims have been amended to state more explicitly that the promoter used in the polynucleotide (either the prototype hTERT sequence or a variant) causes the transcribable sequence to be expressed in cells endogenously expressing TERT. Since the promoter is defined both by structural and functional features, the claims comply with the Written Description Guidelines that did not have it previously.

Claims 1-16 stand rejected as not requiring the cells being treated to actually express TERT. This feature has now been added to the claims.

Claims 1, 2, and 15 stand rejected as encompassing methods of killing cells by expressing a substance that renders the cells more susceptible to toxicity of a drug. These claims have now been split into embodiments in which the expressed gene product (e.g., a toxin) actually kills the cells directly (claims 1-15) and embodiments in which the expressed gene product (e.g., thymidine kinase) renders the cells more susceptible to toxicity of a drug, optionally followed by treatment with the drug (claims 22-32).

The Office Action also questions the efficacy of gene therapy vectors in view of speculations by Crystal (Science 270:404, 1995) and Greco (Frontiers Biosci. 7:d1516, 2002).

In fact, there is quite a large literature validating the use of gene therapy vectors for cancer treatment. For example:

- Ebert et al. (Cancer Gene Ther. 12:350, 2004), Li et al. (J. Gene Med. 8:679, 2006), and Lui et al. (Hu. Gene Ther. 13:177, 2002) reported cancer therapy in mouse models using gene therapy vectors made from vesicular stomatitis virus (VSV), adenovirus, and naked DNA.
- Aghi and Martuza (Oncogene 24:802, 2005) reviewed the experience in Phase I and Phase II human clinical trials in over 300 cancer patients, using constructs made from herpes virus, reovirus, adenovirus, Newcastle Disease virus, and vaccinia.
- Gu et al. (Cancer Res. 5359, 2000) reported results of an adenoviral construct in which the human TERT promoter controlled expression of the genes encoding the toxic gene Bax, in accordance with the invention claimed in this application. The constructs suppressed growth of the human lung cancer cell line H1299 in nude mice. Similarly, Jacob et al. (Cancer Gene Ther. 12, 109, 2005) showed suppression of the growth of pancreatic tumor using a construct in which the TERT promoter controlled expression of the TRAIL gene.
- Irving et al. (Cancer Gene Ther. 11:1274, 2004) and Wirth et al. (Cancer Res. 63:3181, 2003) reported that conditionally replicative viruses (also known as oncolytic viruses) driven by the human TERT promoter provides broad-spectrum antitumor activity without liver toxicity.
- Majumdar et al. (Gene Ther. 8:568, 2001) constructed adenoviral vectors in which a thymidine kinase gene was placed under control of the human TERT promoter, in accordance with this invention. They reported that the TERT promoter drives efficacious tumor gene therapy: expression of thymidine kinase followed by ganciclovir treatment.

Copies of these references are being provided for the Examiner's reading pleasure in an Information Disclosure Statement being filed under separate cover.

Applicant submits that the invention covered by the amended claims is described and enabled in the specification, in the context of contemporary methods of cancer therapy, as has been confirmed in subsequent publications. Withdrawal of these rejections is respectfully requested.

Double patenting

The previously presented claims stand rejected for obviousness-type double patenting over claims 1-19 and 22-23 of U.S. Patent 6,777,203, of which this application is a continuation.

Applicants will file a Terminal Disclaimer or address this issue in an appropriate manner, once claims to otherwise allowable subject matter has been identified in this application.

Pursuant to 37 CFR § 1.56, the Office is hereby reminded of other issued U.S. patents and applications owned by Geron Corporation that claim subject matter related to the human TERT promoter:

USSN	Title	Status	Patent No.
09/402,181	Promoter For Telomerase Reverse Transcriptase	Issued	6,610,839
10/325,810	Regulatory Segments of the Human Gene for Telomerase Reverse Transcriptase	Allowed	
10/674,836	Cancer Therapy Using the Telomerase Promoter	Pending	
10/206,447	Dual Specificity Tumor Killing Vectors Driven by the Telomerase Promoter	Pending	

The Examiner is requested to consider whether any of the subject matter claimed in the patents and patent applications listed above, or any of the prosecution history in the pending applications listed therein, is material to patentability of any claim in the present application.

Request for Interview

Applicant respectfully requests that all outstanding rejections be reconsidered and withdrawn. The application is believed to be in condition for allowance, and a prompt Notice of Allowance is requested.

In the event that the Examiner determines that there are other matters to be addressed, applicant hereby requests an interview by telephone.

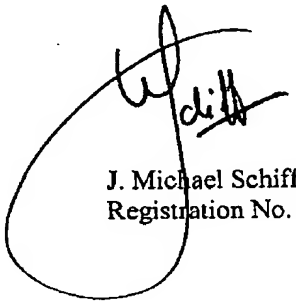
PATENT
USSN 10/674,836
Docket 082/103c

Fees Due

Enclosed with this Amendment is authorization to charge the Deposit Account for the added claims.

Should the Patent Office determine that a further extension of time or any other relief is required for further consideration of this application, applicant hereby petitions for such relief, and authorizes the Commissioner to charge the cost of such petitions and other fees due in connection with the filing of these papers to Deposit Account No. 07-1139, referencing the docket number indicated above.

Respectfully submitted,



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Facsimile Transmittal Sheet

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